DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m40381

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

VIA FEDERAL EXPRESS

Ref: Customs Entry No. M05-0319932-1
Products: Soap, Deodorant, Antiperspirant, EAU de Toilet, Hair Preparations, Lipstick, and Body Lotion

WARNING LETTER

FLA-00-83

August 21, 2000

Jack De Vernejol, President/Owner
JDV International
1971 N.W. 29th Street
Ft. Lauderdale, Florida 33311-2125

Dear Mr. De Vernejol:

The Food and Drug Administration (FDA) attempted to examine a shipment of various products offered for entry into the United States by your firm on July 11, 2000, under the above referenced entry number. FDA requested entry documents and requested the availability of the entry on July 12, 2000. On August 8, 2000, FDA issued a Notice of Sampling for the entry. You have failed to provide the entry documents and the availability of the entry. Title 21, Code of Federal Regulations (21 CFR), Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We have requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food and Drug Administration, Attention: Magda M. Karlsen, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Edward R. Atkins for

Emma R. Singleton
Director, Florida District

Enclosure

cc: Thomas Winkowski
U. S. Customs Service
P. O. Box 02-580
Miami, Florida 33102-5280

J. P. Reynolds Company, Inc.
8410 N.W. 53rd Terrace
#108
Miami, Florida 33166